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APPLICATION NO.	FLING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-704,212	10.31.2000	Wouter E. Roorda	M-9457 US	4669

7590 04/23/2003

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	//

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

HS-11

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/704,212	ROORDA ET AL
Examiner	Art Unit	
	Jennifer Kolb Michener	1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 03 February 2003.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 2,4-18,20-22,29 and 30 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2,4-18,20-22,29 and 30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other _____

## DETAILED ACTION

### ***Election/Restrictions***

1. Examiner acknowledges with appreciation Applicant's cancellation of non-elected claims in Paper #10.

### ***Claim Objections***

2. The objections to claims 1, 17, and 19 are withdrawn based on Applicant's amendments.

### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 12-17 under 35 U.S.C. 112, second paragraph, has been withdrawn based on Applicant's amendments.

*As necessitated by Applicant's amendment, the following new 112 rejections are made:*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29, 2, and 4-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly-added phrase of claim 29, "provided that the hemocompatible coating is not subjected to a dialdehyde cross-linking or stabilization step before in vivo use", appears to be new matter. Examiner is unable to find basis, in the originally-filed disclosure, for such a limitation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29, 2, and 4-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to the same newly-added phrase of claim 29 discussed above, it is not clear whether Applicant is claiming a) the coating is neither subjected to dialdehyde cross-linking nor dialdehyde stabilization or b) the coating is neither subjected to dialdehyde cross-linking nor is it subjected to *any form* of stabilization. It is not clear whether the term dialdehyde is meant to describe just the cross-linking reaction or both the cross-linking and the stabilizing reactions.

#### ***Claim Rejections - 35 USC § 102***

8. Claims 29, 30, 5-11, 18, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu et al. (4,871,357).

Examiner maintains the rejection of claims 5-11, 18, and 21-22.

Examiner necessarily withdraws the rejection of claims 1, 3, and 19 based on Applicant's cancellation of the claim.

Examiner includes newly-added claims 29 and 30 in this rejection because these claims represent reformatted, cancelled claims 1 and 19, respectively, which were originally rejected herein. Regarding the rejection of new limitations of claim 29, Hsu does not require any dialdehyde crosslinking or stabilization. Claim 30 is rejected for the same reasons applied to claims 19 and 7 in the previous office action.

9. Claims 29, 5-7, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Drumheller (5,914,182).

Examiner maintains the rejection of claims 5-7 and 18.

Examiner necessarily withdraws the rejection of claim 1 based on Applicant's cancellation of the claim.

Examiner includes newly-added claim 29 in this rejection because claim 29 represents reformatted, cancelled claim 1, which was originally rejected herein. Regarding the rejection of new limitations of claim 29, Drumheller does not require dialdehyde crosslinking or stabilization.

#### ***Claim Rejections - 35 USC § 103***

10. Claims 2, 4, 12-15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al.

Examiner maintains the rejection.

11. Claims 30 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksson et al. (4,118,485) in view of van Tassel et al. (6,241,710).

Examiner maintains the rejection of claim 22.

Examiner necessarily withdraws the rejection of claims 1, 3, and 19 based on Applicant's cancellation of these claims.

Examiner withdraws the rejection of claims 2, 5, 7-15, and 17-18 based on Applicant's amendment.

Examiner includes newly-added claim 30 in this rejection because claim 30 represents reformatted, cancelled claim 19, which was originally rejected herein. The new limitation in claim 30 is rejected for the same reason as applied to claims 19 and 7 in the previous office action.

12. The rejection of claims 1, 3-6, and 18-21 under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (WO 01/45763) in view of Patnaik et al. (6,338,904) has been withdrawn based on common obligation at the time the instant invention was made.

### ***Response to Arguments***

13. Applicant's arguments regarding the rejections maintained in this Office action have been carefully considered but they are not persuasive.

Applicant has argued that the new limitation "provided that the hemocompatible coating is not subjected to a dialdehyde cross-linking or stabilization step before *in vivo* use" is not new matter.

Examiner disagrees. Contrary to Applicant's arguments, this limitation is not supported expressly, implicitly, or inherently. Applicant admits that "most" of the coatings of his invention don't have the primary amine necessary for dialdehyde crosslinking and such cross-linking would interfere with "virtually all" of Applicant's embodiments. Therefore, the coatings of Applicant do not preclude such crosslinking *in all cases*. Furthermore, even if none of Applicant's exemplary coatings contained primary amines, there would still be no basis for the newly added limitation. The exemplary teachings of some coatings that happen to contain no dialdehyde crosslinking do not provide basis for claiming all possible coatings with no such crosslinking.

Additionally, it appears to Examiner that Applicant's heparin compounds with quaternary ammonium ions contain primary amines.

Applicant argues that Hsu fails to teach that ethanol enhances the solubility of the heparin complex in the solution of the two solvents with the heparin.

Examiner notes that Hsu teaches coating PTFE substrates with the benzyl alkonium ion heparin in a fluoropolymer-wetting alkane solvent and an organic alcohol solvent, just as Applicant claims. Therefore, the organic alcohol solvent of Hsu inherently enhances the solubility of the heparin compound in the two solvents, just as it does in Applicant's invention. Additionally, Eriksson, which was used in the prior office action and above,

teaches that ethanol enhances solubility of such a heparin compound when used in combination with polar cyclohexane (col. 5). Ethanol inherently does the same in the method of Hsu.

Since Hsu teaches all of the limitations of the independent and applicable dependent claims, if there is some difference between Applicant's results and that of Hsu it must be due to some process limitation not claimed in the independent claims.

Applicant argues that Drumheller teaches sequential deposition of a first and second solvent and not a mixture of a first and second solvent.

Examiner disagrees.

Applicant states in his arguments on page 7, that the independent claim does not limit the order of addition of the first solvent, second solvent, and hemocompatible substance. Therefore, the claim does not preclude the sequential deposition of solvents. Furthermore, the first solvent of Drumheller wets the surface for subsequent application of the second solvent and hemocompatible substance. At the time of application of the second solvent and hemocompatible substance, a mixture is formed that contains the first and second solvents and the hemocompatible substance, as required by the claims.

Applicant argues that the Eriksson in view of van Tassel rejection fails to teach the solvents listed in newly added claim 30 (reformatted claim 19 with solvents of claim 7). Examiner disagrees.

The fluoropolymer-wetting cyclohexane of this rejection is a fluoropolymer- wetting alkane, as claimed in claim 30.

***Conclusion***

14. Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
Jennifer Kolb Michener  
April 20, 2003

  
Shrive P. Beck  
Supervisory Patent Examiner  
April 20, 2003